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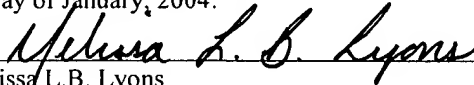
DOCKET NO.: V0179.70000US00

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Erich Wanker et al.  
Serial No: 09/463,874  
Confirmation. No.: 6909  
Filed: June 7, 2000  
For: COMPOSITION AND METHOD FOR THE DETECTION OF  
DISEASES ASSOCIATED WITH AMYLOID-LIKE FIBRIL OR  
PROTEIN AGGREGATE FORMATION  
Examiner: Olga N. Chernyshev  
Art Unit: 1646

CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)

The undersigned hereby certifies that this document is being placed in the United States mail with first-class postage attached, addressed to MAIL STOP Non-Fee Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the 21<sup>st</sup> day of January, 2004.

  
Melissa L.B. Lyons

**Mail Stop Non-Fee Amendment**

Commissioner For Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

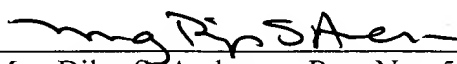
Transmitted herewith are the following documents:

- ☒ **Declaration (executed by Erich Wanker)**
- ☒ **Return Receipt Postcard**

If the enclosed papers are considered incomplete, the Mail Room and/or the Application Branch is respectfully requested to contact the undersigned at (617) 720-3500, Boston, Massachusetts.

A check is not enclosed. If a fee is required, the Commissioner is hereby authorized to charge Deposit Account No. 23/2825. A duplicate of this sheet is enclosed.

Respectfully submitted,  
*Erich Wanker et al., Applicant*

By:   
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Docket No. V0179.70000US00  
Date: January 21, 2004  
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16 Jan 2004 16:07

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DOCKET NO.: V0179.70000US00

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Erich Wanker et al.  
Serial No: 09/463,874  
Confirmation No.: 6909  
Filed: June 7, 2000  
For: NOVEL COMPOSITION AND METHOD FOR THE DETECTION  
OF DISEASES ASSOCIATED WITH AMYLOID-LIKE FIBRIL OR  
PROTEIN AGGREGATE FORMATION  
Examiner: Olga N. Chetyshev  
Art Unit: 1646

CERTIFICATE OF MAILING UNDER 37 C.F.R. 81.8(a)

The undersigned hereby certifies that this document is being placed in the United States mail with first-class postage attached, addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the 21<sup>st</sup> day of January, 2004.

*Melissa L. B. Lyons*  
Melissa L. B. Lyons

Commissioner For Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

DECLARATION

I, ERICH WANKER, declare as follows.

1. I make this Declaration in support of U.S. Patent Application Serial No. 09/463,874, on which I am an inventor. I have reviewed the specification and pending claims of U.S. Serial No. 09/463,874. I have also reviewed the Office Action dated July 29, 2003.
2. The Office Action rejects claims 1-6 and 8-11 "as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention." The basis of the rejection is the unpredictability of identifying and using fusion proteins encompassing components other than GST and huntingtin and the purported lack of description of these components in the specification.
3. I disagree with the rejection. The description of the fusion protein in the specification is sufficient to enable one of skill in the art to practice the invention over the entire claimed range.

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Serial No.: 09/463,874  
Docket No.: V00179.70000  
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4. The claimed invention is a nucleic acid encoding a fusion protein that has two main components: a polypeptide that enhances solubility and/or prevents aggregation of the fusion protein and an amyloidogenic polypeptide that has the ability to self-assemble into amyloid-like fibrils or protein aggregates.
5. The specification broadly describes the class of compounds. We, the inventors, have described the preferred properties of the genus of compounds in detail in the specification on pages 6-11. Specific examples of the members of those classes is set forth on page 8 and 11. A specific working example which embodies a preferred species of the invention is used to exemplify the class of compounds. The claims, however, are not limited to such compounds. Based on the description, one of skill in the art would be able to substitute into the fusion protein the other specific polypeptides described and listed in the specification that have the claimed properties. These are known polypeptides that have been described previously and functional variants thereof. The invention is based on the production of the fusion protein. The individual polypeptide components of the fusion protein are not new. Based on the properties described in the specification one of skill in the art is enabled to practice the claimed invention. It is not unpredictable as asserted by the Examiner.
6. I, the undersigned declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with the knowledge that willful, false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful, false statements may jeopardize the validity of this document and any patent which may issue from the above-identified patent application.

Date:

BERLIN  
16/1/04

Signature

ERICH WANKER  
Typed Name